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**FACSIMILE SUBMISSION UNDER 37 CFR 1.8**

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TO:	FROM:
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RE:	APPLICATION SERIAL NUMBER:
Response to Restriction Requirement dated October 25, 2006	10/663,570

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Luc R. Mongeon; Jesus Casas-Bejar; H. Toby Markowitz; Daisy P. Cross; Janelle Blum; Michael Ebert; Timothy G. Laske Confirmation No. 2842

Serial No.: 10/663,570

Filed: September 15, 2003 Customer No.: 28863

Examiner: Michael William Kahelin

Group Art Unit: 3762

Docket No.: 1023-203US01

Title: DELIVERING GENETIC MATERIAL TO A STIMULATION SITE

CERTIFICATE UNDER 37 CFR 1.8 I hereby certify that this correspondence is being transmitted via facsimile to the United States Patent and Trademark Office on November 22, 2006.

By: Shirley A. Betlach  
Name: Shirley A. Betlach

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents  
Alexandria, VA 22313-1450

Dear Sir:

This response is to the Office Action mailed October 25, 2006. Claims 1-3 and 9-42 have been restricted under 35 U.S.C. § 121 as follows:

- I. Claims 1-3 and 9-34, drawn to a device/method for delivering genetic material.
- II. Claims 35-42, drawn to a method of manufacturing a lead.

Applicants hereby elect Group I with traverse. Applicant respectfully notes that claim 4 is pending, and submits that claim 4 is also included in Group I.

In addition, Applicant acknowledges that claims 43-45 have been withdrawn from consideration as being drawn to a non-elected invention pursuant to M.P.E.P. § 821.03.

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### **Traversal**

According to MPEP § 803, there are two criteria for a proper requirement for restriction between patentably distinct inventions: (A) The inventions must be independent (see MPEP § 802.01, § 806.04, § 808.01) or distinct as claimed (see MPEP § 806.05 - § 806.05(i)); and (B) there must be a serious burden on the examiner if restriction is required (emphasis added).

### ***No Serious Burden***

Applicant believes that there is no serious burden on the Examiner with respect to examination of the claim of Group II in addition to the claims of elected Group I, because many of the elements of the dependent claims are substantially similar. Thus, although the independent claims of each of the Groups differ in scope, there is no serious burden on the Examiner with respect to examination of claims 1-4 and 9-42, and the restriction should be withdrawn.

### ***Process of Making/Product Made***

In support of the restriction between Group I and Group II, the Examiner cited MPEP § 806.05(f), which states that a process of making and a product made by the process can be shown to be distinct inventions if either or both of the following can be shown: (1) that the process as claimed is not an obvious process of making the product and the process as claimed can be used to make another materially different product, or (2) that the product as claimed can be made by another materially different process. The Examiner then stated "in the instant case, the genetic material could be introduced into the matrix after the matrix is in the chamber." (Office Action at page 3, item 5.)

Applicant traverses this restriction. Nothing in independent claim 35 (Group II) requires the genetic material to be introduced into the matrix prior to placing the matrix into a chamber. Rather, independent claim 35 of Group II generally recites a method comprising "introducing genetic material to a polymeric matrix" and "placing the matrix into a chamber . . ." As is well known, "unless the steps of a method actually recite an order, the steps are not ordinarily construed to require one." *Loral Fairchild Corp. v. Sony Corp.*, 181 F.3d 1313, 1322, 50 USPQ.2d 1865, 1870 (Fed. Cir. 1999). Accordingly, the claims directed at the process of making a product (Group II) are not limited to a method in which a genetic material is introduced into a

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polymeric matrix before the matrix is introduced into the chamber. Thus, the allegedly "materially different" process for making the product of the claims of Group I proposed by the Office Action is in fact within the scope of the claims of Group II. Consequently, the restriction between Group I and Group II is improper and should be withdrawn.

Please charge any additional fees or credit any overpayment to deposit account number 50-1778.

Date:

By:

November 22, 2006  
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